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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,353	11/27/2000	Yen Choo	PM273884	8682

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EXAMINER

WESSENDORF, TERESA D

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 12/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/646,353

Applicant(s)

CHOO ET AL.

Examiner

T. D. Wessendorf

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1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,5-22,24 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,4,23,25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II in Paper No. 16 is acknowledged. The traversal is on the ground(s) that the claims of Group IV, particularly claim 19 has been amended so that they depend from the elected group II, claim 3 or claim 4, and thus include all the elements of Group II. This is not found persuasive because Group II, claim 3 or 4 does not include the feature step as presently claimed in the amended claim 19 of Group IV and therefore, would require additional search and/or consideration.

The requirement is still deemed proper and is therefore made FINAL.

Applicants' election with respect to species, as recited in claim 4, is noted. In view of the prior art of record, discussed below, the restriction with respect to this species election (different mutations) is withdrawn. However, the restriction with respect to the species of the different zinc-finger DNA binding protein is maintained. Applicants' election of the species, Zif268, without traverse, is acknowledged.

Claims 1-2, 5-22 and 26-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable

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generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 16.

Drawings

The drawings are objected to because Figure 1b at page 13, line 31, recites the sequence GCGGNGGCG that does not correspond with the peptide sequence in the drawings figures (1b) which recites GCGGMGGCG. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required. Applicants cannot use the abstract of the PCT application.

The disclosure is objected to because of the following informalities: the subscripts in the peptide sequence at page 7, lines 6 and 15 are undecipherable.

Appropriate correction is required.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors [typographical, grammatical (see e.g., page 7, lines 31-32) and

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idiomatic errors]. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication recited at e.g., page 6, line 32 up to page 7, lines 3 is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Applicants are requested to check for other incorporation of essential materials in the specification since they are too numerous to mention specifically.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-4, 23, 25-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the steps of making a DNA binding polypeptide of the Cys-His2 zinc finger protein. The claim recites for the binding property of the zinc finger protein but not the process of preparing said protein.

The conditional requirement recited in claim 4 is indefinite especially as applied to a process of making, especially in the absence of positive teachings in the disclosure for said conditional requirements. The negative limitation "is not Asp" is indefinite as to the residues it includes or excludes. The terms "may be"; "and/or" fails to ascertained the claimed invention with precision. It is suggested that applicants delete the term "may be" or clearly set forth whether the residues are combined or not. The term "small" is not defined by the claim (4), the specification does

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not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

B. Claim 23 is unclear as to the limitation "the binding protein comprises two more zinc finger motifs, placed N-terminus to C-terminus." Is the peptide sequence comprised of all the motifs joined one after the other from the N-terminus?

C. The limitation in claim 26 of further subjecting the DNA binding protein to one or more rounds of randomization and selection in order to improve the characteristics thereof is indefinite since neither claim 3 or 4 contains any process steps of randomization and selection. Further, claim 3 or 4 does not recite for any characteristic of the DNA binding protein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or

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inventor's certificate filed more than twelve months before the filing of the application in the United States.

Claims 3, 4, 23, 25-26 are rejected under 35 U.S.C. 102(a) as being anticipated by Choo (Comment, XP-002116419).

Choo discloses a recombinant method of preparing a DNA binding protein of the Cys2-His2 zinc finger protein to MeC of the DNA triplet by Ala at position 3 of the zinc finger protein using phage display method. See the entire article, pages 265-266.

The limitation of claim 4 is disclosed at page 266, col. 1 which recites the zinc finger DNA recognition rules, as recited in claim 4. The claimed method of preparing a DNA binding protein of Zinc finger protein with Ala at position 3 is fully met by the method of Choo using the recombinant phage method. [It appears that Choo made this method only by himself since the article repeatedly uses the pronoun "I" instead of "we", by the present inventors).

Claim 23 is disclosed at page 266, Fig. 1 which shows the placement of the motif in the zinc finger protein or class.

Claim 26 is disclosed at page 267, col. 1 which recites the five rounds of selection after randomization of the residues using phage display method.

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Claims 3, 4, 23, 25-26 are rejected under 35 U.S.C. 102(d) as being anticipated by Choo (United Kingdom 9805576.7).

Choo discloses a recombinant method of preparing a DNA binding protein Cys2-His2 with Ala at position 3 specifically binding to meC of the DNA triplet using the phage display method. See the entire United Kingdom Application. [The United Kingdom application cites Choo only as the inventor as opposed to the instant application having Isalan as a co-inventor].

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 4 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being

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unpatentable over claim 3 of copending Application No.

09/424,488. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant broadly claimed method of making the DNA binding protein encompasses the specific method steps of the copending method of making the DNA zinc finger protein. The conditional ("if") substitutions of the instant method overlaps or is included in the copending application. [It is not seen how the method of making is affected by said conditional requirements].

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants are requested to provide the examiner with copies of the other co-pending application claims. It appears that there are numerous copending applications related to the instant application.

No claim is allowed.

REASSIGNMENT OF LOCATION

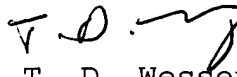
The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1639.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
December 27, 2002